K003030

BIO-RAD **Bio-Rad Laboratories**

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

NOV 2 9 2000

510(k) Summary

Submitter
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Irvine, CA 92618
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Contact Person
Elizabeth Platt

Date of Summary Preparation
September 28, 2000

Device (Trade & Common Name)
Lyphochek Hemoglobin $A1_c$ Linearity Set

Classification Name
Class II, CFR 864.8625: Control, Hemoglobin
81GGM

Devices to Which Substantial Equivalence is Claimed

Lyphochek Diabetes Control
Bio-Rad Laboratories
Irvine, CA
K862186A1

Abbott Architect Ferritin MasterCheck
Manufactured for Abbott Laboratories
Abbott Park, IL
K984325

Statement of Intended Use
Lyphochek Hemoglobin $A1_c$ Linearity Set is intended to verify the linearity throughout the patient reportable range of Hemoglobin $A1_c$ assays using protocols established in individual laboratories.

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Description of the Device

Lyphochek Hemoglobin $A1_C$ Linearity Set is prepared from human whole blood and contains preservatives and stabilizers. The control is provided in lyophilized form for increased stability.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Lyphochek Hemoglobin $A1_C$ Linearity Set and the devices to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Hemoglobin $A1_C$ Linearity Set (New Device)	Bio-Rad Lyphochek Diabetes Control and Abbott Architect Ferritin MasterCheck (Substantially Equivalent Devices)
Intended Use	A linearity set intended to verify the linearity throughout the patient reportable range of Hemoglobin $A1_C$ assays using protocols established in individual laboratories.	Lyphochek Diabetes Control: An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. Abbott Architect Ferritin MasterCheck: Ferritin MasterCheck is intended for use in the verification of sensitivity, calibration linearity, and reportable range of the Ferritin assay on the Abbott Architect *i* System.
Form	Lyophilized	Lyophilized; Liquid
Open Vial Claim	7 days when stored tightly capped at 2-8°C.	Lyphochek Diabetes Control: 7 days when stored tightly capped at 2-8°C. Abbott Ferritin Mastercheck: Once opened, this liquid product will be stable for 3 days.
Matrix	Human whole blood	Lyphochek Diabetes Control: Human whole blood Abbott Architect Ferritin MasterCheck: Ferritin (human) prepared in HEPES buffer with protein (bovine) stabilizers.

Storage	2-8°C	2-8°C
Analytes	Hemoglobin $A1_c$	Lyphochek Diabetes Control: Hemoglobins $A1_c$, A1, F, and Total Glycated Abbott Architect Ferritin MasterCheck: Ferritin, HEPES buffer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 9 2000

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K003030
Trade Name: Lyphochek ~~Hemoglobin $A1_c$ Linearity Set~~
Regulatory Class: II
Product Code: GGM
Dated: September 28, 2000
Received: September 28, 2000

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K003030

Device Name: Lyphochek Hemoglobin $A1_c$ Linearity Set

Indications for Use:

Lyphochek Hemoglobin $A1_c$ Linearity Set is intended to verify the linearity throughout the patient reportable ~~range of Hemoglobin $A1_c$ assays using~~ protocols ~~established in~~ individual laboratories.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices K003030
510(k) Number

Prescription Use ✓ OR Over-The Counter Use _____